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**Date:** June 30, 2008

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**From:** Deirdre E. Sanders, Esq.

**Subject:** Supporting Document for Reply to Office Action dated  
December 28, 2007

**Docket No.:** 3518.1012-005

**Applicant:** DePuy Spine, Inc.

**Application No.:** 10/714,594

**Filing Date:** November 14, 2003

Number of pages including this cover sheet: 12

Please confirm receipt of facsimile: Yes ☒ No ☐

**Comments:**

Attached is a supporting document for Reply to Office Action dated December 28, 2007:

CV of Mohamed Amr Attawia

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## **Mohamed Amr Attawia**

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### **Education**

|           |  |
|-----------|--|
| 1978 M.D. | School of Medicine, Cairo University, Cairo, Egypt                               |
| 1987 M.S. | Department of Biomedical Science, Northeastern University, Boston, Massachusetts |

### **Professional Employment and Training**

|              |   |
|--------------|---|
| 2008-Present | Vice President, Product Development, Osteotech Inc., Eatontown, New Jersey                            |
| 2007-2008    | Senior Director, Product and Business Development, Osteotech Inc., Eatontown, New Jersey              |
| 2005-2006    | Principal Scientist/Disc Group Manager<br>DepuyBiologics, Johnson & Johnson<br>Raynham, Massachusetts |
| 2001-2005    | Staff Scientist<br>DepuyAcromed, Johnson & Johnson<br>Raynham, Massachusetts                          |

### ***Industrial Experience:***

*Responsible for assuring technical integrity, project planning, budget projections, resource allocations, identifying top leading academic centers for collaboration, and updating surgeons/senior management.*

*Technical responsibilities include the development, design, management, and implementation of studies to determine product opportunities, demonstrate concept feasibility, establish product specifications, and conduct process verifications and validations.*



*All activities require an advanced understanding of cell culture systems, pre-clinical testing, shelf life, process changes, histology, cell characterization techniques, animal surgery and modeling, and pre-clinical in vivo evaluations.*

*These efforts led to the launch of several 510k products, such as Conduit (Synthetic bone graft) and Collect (Stem cell therapy).*

*Led a new program aimed at developing novel approaches for the treatment of degenerative disc diseases (DDD) using a number of regenerative and anti-inflammatory drugs. The program includes preclinical studies at various academic sites. This study led to an IND submission.*

*Currently leading the product and business development team at Osteotech Inc.*

|              |  |
|--------------|--|
| 1998-2003    | Research Associate Professor<br>Chemical Engineering, Drexel University<br>Philadelphia, Pennsylvania  |
| 1998-2001    | Deputy Director, Center for Advanced Biomaterials<br>and Tissue Engineering, Drexel University<br>Philadelphia, Pennsylvania                               |
| 1999-Present | Visiting Research Associate Professor<br>School of Biomedical Engineering, Sciences and<br>Health Systems, Drexel University<br>Philadelphia, Pennsylvania |
| 1994 - 1998  | Research Assistant Professor<br>Department of Orthopaedic Surgery<br>Allegheny University of Health Sciences<br>Philadelphia, Pennsylvania                 |
| 1994 - 1996  | Visiting Research Scientist, Harvard-MIT<br>Division of Health Sciences and Technology<br>Cambridge, Massachusetts   |
| 1992-1994    | Postdoctoral Research Associate, Harvard-MIT<br>Division of Health Sciences and Technology<br>Cambridge, Massachusetts                                     |
| 1991-1992    | Postdoctoral Fellow, Endocrine Unit<br>Massachusetts General Hospital<br>Boston, Massachusetts   |



|           |  |
|-----------|--|
| 1987-1991 | Practical Training/Postdoctoral Fellow<br>Section on Immunology<br>Joslin Diabetes Center<br>Harvard Medical School<br>Boston, Massachusetts       |
| 1985-1987 | Ph.D. Candidate/Postdoctoral Fellow<br>Department of Pathology, New England<br>Deaconess Hospital, Harvard Medical School<br>Boston, Massachusetts |
| 1983-1985 | English Language Studies, ELS<br>Los Angeles, California<br>Biochemistry Courses, Boston University<br>Boston, Massachusetts                       |
| 1981-1983 | Attendant, Department of Pediatrics and Internal<br>Medicine, Baadani Hospital<br>Baadan, North Yemen  |
| 1980-1981 | Resident, Department of Medicine and Clinical<br>Pathology, Minister of Health<br>Cairo, Egypt   |
| 1979-1980 | Internship, Cairo University Hospitals, Cairo, Egypt   |

#### **Awards and Honors**

|           |   |
|-----------|---|
| 2002      | Johnson & Johnson Standards of Leadership Award   |
| 2001      | Awarded the 10 <sup>6</sup> Award by Drexel University  |
| 1999-2003 | National Science Foundational, Research-<br>Curriculum Development in Tissue Engineering,<br>Co-Principal Investigator              |
| 2001-2003 | U.S.-Egypt Joint Science and Technology Grant<br>Principal Investigator   |
| 1998-2000 | National Institute of Health, Tissue Engineered<br>System for Anterior Cruciate Ligament<br>Regeneration, Co-Principal Investigator |



|               |   |
|---------------|---|
| 1997-1999     | Allegheny University of the Health Sciences,<br>Controlled Delivery of Radiosensitizers, Principal Investigator                                   |
| 1997-1998     | National Institute on Aging, Age Related Effects of Fracture Non-Union Treatment Using a Novel Synthetic Bone Replacement, Principal Investigator |
| 1997-1998     | National Institute on Aging, Age Related Effects on Osteoblast Functions, Principal Investigator  |
| 1997-2001     | National Science Foundation, Development of Bioerodible Polymer Matrices for Osteoblast Growth and Maturation, Co-Principal Investigator          |
| 1996 and 2002 | Lead Articles, Journal of Biomedical Materials Research (JBMR)  |
| 1983          | Scientific Scholarship from United Arab Emirates  |

#### **Membership of Professional Societies**

|                |   |
|----------------|---|
| 1997           | Work Group for Educational Programs Leading to the M.D. Degree and Resources for Educational Programs, Allegheny University Hospitals |
| 1994 - Present | Society for Biomaterials  |
| 1997-Present   | Orthopaedic Research Society  |
| 1985 - 1994    | American Society for Microbiology   |
| 1980 - Present | Egyptian Medical Syndicate  |

#### **Teaching Experience**

|                |  |
|----------------|--|
| 2000 - 2001    | Instructor, Drexel University<br>"Advanced Cell Biology in Tissue Engineering" |
| 1995 - Present | Co-Instructor, Drexel University,<br>"Tissue Engineering"                      |
| 1995 - 1997    | Co-Instructor, Allegheny University of the Health Sciences                     |



**"Basic Science Course in Orthopaedic Surgery" (for Residents)**

2001- Present      Depuy Spine Sale's training (national and international)

**Activities at National Level**

|                |  |
|----------------|--|
| 2001-2002      | Chair, Society for Biomaterials<br>Drug Delivery Special Interest Group                          |
| 1997 - 2001    | Vice-Chairperson, Society for Biomaterials<br>Drug Delivery Special Interest Group               |
| 1999           | Panel Reviewer, National Science Foundation<br>Biosystems at the Nanoscale                       |
| 1997           | Consultant, National Space Biomedical Research<br>Institute Muscle Alterations and Atrophy Panel |
| 1996 - Present | Member, Society for Biomaterials<br>Biotechnology Special Interest Group (BSIG)                  |
| 1995 - Present | Member, Center for Immunology<br>Allegheny University of the Health Sciences                     |
| 1994 - Present | Member, Institute on Aging<br>Allegheny University of the Health Sciences                        |

**Sessions Moderated/Organized/Chaired**

|      |  |
|------|--|
| 1997 | Society for Biomaterials<br>Drug Delivery General Session  |
| 1997 | Allegheny University of the Health Sciences<br>Clinical Research Center Conference<br>Medical and Surgical Devices Session |
| 1997 | Materials Research Society<br>Symposium Organizer<br>Polymers in Orthopedics   |
| 1998 | Society for Biomaterials   |



### Advances in Drug Delivery Symposium

- 2000 American Standard Material Testing
- 2000 Distance Learning in Modern Medicine, Cairo, Egypt
- 2002 Society for Biomaterials  
Drug Delivery General Session

### Ph.D. Theses Mentored

Mark Borden (1999) Biomedical Engineering-Drexel University, Saadiq El-Amin (2002) Cell and Molecular Biology-T. Jefferson University, James Cooper (2003) Biomedical Engineering-Drexel University, Yusuf Khan (2003) Biomedical Engineering-Drexel University, Michel Kofron (2003), Biomedical Engineering-Drexel University, Swaminathan Sethuraman (2005) Chemical Engineering-Drexel University.

### MS and BS Mentored Students

Jessica Deven (1993) Chemical Engineering-MIT, Miranda Fan (1994) Chemical Engineering-MIT, Michael Wong (1994) Chemical Engineering-MIT,

### PUBLICATION

1. Nayak RC, Attawia M, Cahill CJ, Ohashi H, King GL. A monoclonal antibody (3G5) defined ganglioside antigen is expressed by renal glomerular epithelial cells (podocytes). Kidney International vol. 41, No. 6 Jun. 1992 p1638-1645.
2. Eid H, Smith TW, Attawia M, Nayak RC, Kelly R. Plasticity of adult rat cardiac myocytes in long term culture: Role of non-muscle cardiocyte. Circulation Research vol. 71, No.1, Jul. 1992 p40-50.
3. Attawia, M., Devin, J., and Laurencin, C.: Immunofluorescence and Confocal Laser Microscopy Studies of Osteoblast Growth and Phenotypic Expression in Three-



- Dimensional Degradable Synthetic Matrices. J. Biomed Mater. Res. 29:843-848 (1995)
4. Attawia, M.A., Uhrich, K.E., Botchway, E., Fan, M., Laurencin, C.T., and Langer, R. Cytotoxicity testing of poly(anhydride-co-amides) for orthopaedic applications. J. Biomed. Mater. Res. 29:1233-1240 (1995)
  5. Laurencin, C, El-Amin, S., Ibim, S., and Attawia, M. Allcock, H., and Ambrosia, A.: A highly porous 3-dimensional polyphosphazene matrix for bone regeneration. J. Biomed. Mater. Res. 30: 133 - 138 (1996)
  6. Devin, J., Attawia, M., and Laurencin, C.: Three-Dimensional porous polymer-ceramic matrices for use in bone repair. J. Biomat. Sci. (Polymer Edition) 7(8):661-669 (1996)
  7. Attawia, M.A., Uhrich, K.E., Botchway, E., Langer, R., and Laurencin, C.T.: In vitro bone biocompatibility of poly(anhydride-co-imides) containing pyromellitylimidoalanine J. Ortho. Res. 14(3):445-454 (1996)
  8. Laurencin, C.T., Attawia, M.A., and Herbert, K.M.: Osteoblast-like cell adhesion, migration and mineralized matrix formation on porous polymer-ceramic systems for bone regeneration. Proc. Mater. Res. Soc. 213:639-644,(1995)
  9. Attawia, M.A., Herbert, K.M., and Laurencin, C.T.: Osteoblast-like cell adherence and migration through 3-dimensional porous polymer matrices. Biochem. Biophys. Res. Comm. 213:639-644, (1995)
  10. Dotta F, Bonner-Weir S, Appel MC, Cahill CJ, Ede G, O'Neill JJ, Attawia M. Hattori M, Nayak RC, Eisenbarth GS. Identification of an anti-insulinoma antibody associated with islet autoimmunity in man and non-obese diabetic mouse. Diabetes (Submitted to Diabetes).
  11. Attawia M. Nayak RC, Circulating anti-pericyte autoantibody in diabetic retinopathy. Retina. 19:390-400 (1999)
  12. H. Ohashi , Attawia MA , G. L. King , Receptors For Insulin- Like growth factor II (IGF-II) and binding proteins in the cultured bovine glomerular endothelial cells. (Submitted to Endocrinol.)
  13. Laurencin, C., Attawia, M., Elgendy, H., Uhrich, K., Ibim, S., and El-Amin, S.: Tissue engineering of bone using degradable polymeric materials. Portland Bone Symposium, 533-552 (1995)



14. Laurencin, C.T., Attawia, M.A., Elgendy, H. and Herbert, K.M.: Tissue engineered bone-regeneration using degradable polymers: the formation of mineralized matrices. Bone 19:93S - 99S (1996)
15. Laurencin, C.T., Borden, M.D., Attawia, M.A., Ko, f., and Morrill, G.M.: Polymer based tissue engineering of bone. Polymer Preprints 39 (2) 122-123, 1998
16. Laurencin, C., Attawia, M.A., Attia, E., Warren, R.F., Jannafin, J., and Botchwey, E.: The development of cell-material systems for anterior cruciate ligament regeneration: Soft tissue cell adhesion on polymeric surfaces. In Vitro, 34, 90-92, 1998
17. Attawia, M.A., Nicholson, J.J., and Laurencin, C.T.: A Novel Co-Culture System to Evaluate the Biocompatibility of Orthopaedic Materials. Clin. Ortho. and Rel. Res. 365, 230-236, 1999
18. Attawia, M.A., Uhrich, K., Herbert, K.M., Langer, R., and Laurencin, C.T.: Proliferation, morphology, and protein expression by osteoblasts cultured on poly(anhydride-co-imides). Applied Biomater. 48, 322-327, 1999
19. Attawia, M., Devin, J., and Laurencin, C.: Osteoblast Growth in Degradable 3-Dimensional Matrix Systems: Immunofluorescence and Confocal Laser Microscopy Studies. J. Biomed Mater. Res. 29:843-848, (1995)
20. Laurencin, C.T., Ko, F.K. Attawia, M.A., Borden, M.: Studies on the development of a tissue engineered matrix for bone regeneration. Cells and Materials 8: 175-181 (1998)
21. Laurencin, C.T., Attawia, M.A., Borden, M.D.: Advancements in tissue engineered bone substitutes.: Current Opinion in Orthopaedics 10:445-451 (1999)
22. Laurencin, C.T., Attawia, M.A., Borden, M., Lu H.L., and Lieberman, J.R.: Poly(lactide-co-glycolide)/Hydroxyapatite Delivery of BMP-2-Producing Cells: a Regional Gene therapy Approach to Bone Regeneration Biomaterials, 22, 1271-1277, 2001
23. Attawia, M.A., Herbert, K.M., Borden, M.D., Asrari, F., Uhrich, K.E., and Laurencin, C.T.: A novel drug delivery approach for treating Ewing's Sarcoma. J. Controlled Release, 71, 193-202, 2001
24. Borden, M., Attawia, M., Khan, M.Y., Laurencin, C.T.: Tissue Engineered Microsphere-Based Matrices for Bone Repair: Design, Evaluation, and Structural Optimization, Biomaterials, 23, 551-559, 2001



26. El-Amin, S.F., Attawia, M.A., Lu, H.L., Shah, A.K., Chang, R., Hickok, N.J., Tuan, R.S., and Laurencin, C.T.: Human Osteoblast Integrin Expression on Degradable Polymeric Materials for Tissue Engineered Bone J. Orth. Res. 20, 20-28, 2002
27. Laurencin, C.T., Ko, F.K., Borden, M.D., Cooper, J., Li, W.L., and Attawia, M.A.: Fiber based tissue engineered scaffolds for orthopaedic applications: In vitro cellular response. Proc. Mater. Res. Soc., in press
28. Borden, M., Attawia, M., Khan, M.Y., Laurencin, C.T.: The Sintered Microsphere-Based Matrices for Bone Tissue Engineering: In vitro osteoconductivity studies. J. Biomed. Mater. Res. 61, 421-429, 2002
29. El-Amin, S.F., Attawia, M.A., Lu, H.L., Shah, A.K., Khan, Y., Chang, R., Hickok, N.J., Tuan, R.S., and Laurencin, C.T.: Integrin expression human osteoblasts cultured on degradable polymeric materials applicable for tissue engineered bone. J Ortho Res 2002;20(1):20-28
30. El-Amin, S.F., Lu HH, Attawia, M.A., Shah, A.K., Chang, R., Tuan, R.S., and Laurencin, C.T.: Extracellular matrix production by human osteoblast culture on biodegradable polymers applicable for tissue engineering. Biomaterials 2003; 24 (7):1213-1221.
31. Borden, M., El-Amin, S.F., Attawia, M.A., Laurencin, C.T.: Structural and human cellular assessment of a novel microsphere based tissue engineered scaffold for bone repair, Biomaterials, in press
32. Laurencin CT, Attawia M, Karti DS, Khan Y, Marcolongo M, Ko F, Sun W. Toward an International Tissue Engineering Curriculum: The Drexel Initiative. Proceedings of the American Society for Engineering Education, 2793, 2003
33. Attawia, M., Kadiyala, S., Fitzgerald, K., and Bruder, S.: The Rational Selection of Bone Graft Substitutes Points Toward a Simple, Autologous Cell-Based Therapy, Bone Graft Substitutes / Cato Laurencin, editor. AAOS/ASTM, 2003
34. Borden, M., Attawia, M., Khan, M.Y., Laurencin, C.T.: Bone Formation In Vivo Using a Novel Sintered Polymeric Microsphere Matrix, JBJS (br), (In Press)
35. Kofron, M., Attawia, M., and Laurencin, C.T.: Cryopreservation of tissue engineered construct for bone: J. Orth. Res. 21, 1005-1010, 2003



36. El-Amin, S.F., Kofron, M., Attawia, M., Lu, HH., Tuan R.S., Laurencin, C.T. Molecular regulation of osteoblasts for tissue engineered bone repair. Clin Orthoo Relat Res 2004;(427):220-225
37. Lu, H., Cooper, J., Manuel, J., Attawia, M., Ko, F., and Laurencin, C.: ACL regeneration using braided biodegradable scaffolds, Biomaterials (In Press)
38. Bergeron, JA; Eskey, CJ; Attawia, M.; Patel, SJ; Ryan, TP; Pellegrino, R; Sutton, J; Crombie J; Paul, BT; Hoopes, PJ: Fluoroscopic-guided radiofrequency ablation of the basivertebral nerve: application and analysis with multiple imaging modalities in an ovine model. Proc. of SPIE Vol. 5698, 156-167, 2005 (Invited Paper)
39. Elisa C. Bass; William H. Nau; Chris J. Diederich; Ellen Liebenberg; Richard Shu; Richard Pellegrino; Jeffrey Sutton; Mohamed Attawia; Serena S. Hu; William T. Ferrier; Jeffrey C. Lotz: Intradiscal thermal therapy does not stimulate biologic remodeling in an in vivo sheep model, Spine 31, 139-145, 2006
40. Brodke D, Pedrozo H, Kapur T, Attawia M, Kraus K, Holy C, Kadiyala S, Bruder S : Bone Grafts Prepared With Selective Cell Retention Technology Heal Canine Segmental Defects as Effectively as Autograft. J. Orth. Res 2006 (In Press)
41. Hujo T, An H, Akeda K, Miyamoto K, Muehleman C, Attawia M, Andersson G, Masuda K: Effects of growth differentiation factor-5 (GDF-5) on the intervertebral disc. In vitro bovine study and in vivo rabbit disc degeneration model study, Spine (In Press)
42. Akeda K, An H, Attawia M, Miyamoto K, Eugene J-M.A. Thonar E, Lenz M, Sah R, Masuda K: Platelet-rich Plasma Stimulates Porcine Articular Chondrocyte Proliferation and Matrix Biosynthesis, Osteoarthritis and Cartilage (In Press)
43. William H. Nau; Chris J. Diederich; Elisa C. Bass; Richard Shu; Jeffrey Sutton; Serena S. Hu; William T. Ferrier; Jeffrey C. Lotz; Mohamed Attawia Richard Pellegrino: Intradiscal Thermal Therapy Using Interstitial Ultrasound: An In Vivo Investigation in Ovine Cervical, Spine (In Press)

## Presented Papers

More than seventy papers presented in national and international meetings



## **Patents**

1. Laurencin, C., Devin, J., and Attawia, M.: Degradable 3-Dimensional Polymeric-hydroxyapatite Bone Composite: Formulation: 5,626,861,
2. Laurencin, C., Devin, J., and Attawia, M.: Degradable 3-Dimensional Polymeric-hydroxyapatite Bone: US Patent No: 5,766,618
3. Laurencin, C.T., Lu, H.L., Kofron, M., Attawia, M. A., and El-Amin, S.E.; Muscle-Polymer Constructs for Bone Regeneration. U.S. Patent Pending
4. Laurencin, C.T., Cooper, J., Ko, F.K., Attawia, M., and Lu, H.: Ligament replacemer constructs and methods for production and use thereof. U.S. Patent Pending

**More than 40 invention disclosures and patent applications filed through J&J Company.**